IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ACTIQ SALES AND MARKETING PRACTICES LITIGATION	No. 07-CV-4492 (PBT) Honorable Petrese B. Tucker

PLAINTIFFS' RESPONSE IN OPPOSITION TO MOTION TO EXCLUDE THE DECLARATION AND TESTIMONY OF MEREDITH ROSENTHAL

REDACTED VERSION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

I. INTRODUCTION

Retained to calculate damages for Plaintiffs' and the Class's unjust enrichment claims, Dr. Meredith Rosenthal calculated the profits to be disgorged as a result of Cephalon's illegal, off-label marketing scheme for the sale of the drug Actiq. All of Cephalon's challenges to Dr. Rosenthal's profit calculation go to the weight, rather than the admissibility, of her opinion.

First, she is qualified to calculate and opine on damages. As an economist whose academic and professional focus is the economics of the healthcare industry, and with her actual experience using profit and loss statements and balance sheets, Dr. Rosenthal has the specialized expertise required under Rule 702. Contrary to Cephalon's arguments, courts have rejected the notion that only a certified public accountant is qualified to calculate profits.

Second, her class-wide method for calculating damages is reliable. Dr. Rosenthal's task was to calculate damages for the Class under a theory of disgorgement of the Actiq-specific profits, determined by deducting Actiq-attributable costs from Actiq revenues. Cephalon's desire to deduct additional overhead costs in order to reduce the damages award is a question of fact to be weighed by the jury (and is a class-wide question).

Further, in accordance with the terms of the Risk Management Program ("RMP"), Dr. Rosenthal limited the damages to those Actiq profits attributable to the Class's payments for off-label sales in excess of 15%. While Cephalon contends that the data used to calculate the 15% is not reliable for this purpose (although it admits the data is otherwise reliable), Dr. Rosenthal used the gold-standard data source in the industry: IMS Health's National Disease and Therapeutic Index ("NDTI") – which the FDA and Cephalon agreed should be used *for this very same purpose* in the RMP.

Finally, Dr. Rosenthal's opinion "fits" the facts of this case. She did not offer an opinion on causation but calculated damages in the form of disgorgement of profits for Plaintiffs' unjust

enrichment claims. Cephalon's contention that her opinion does not "fit" because she did not consider the "equities" is a red herring. The purported equities Cephalon cites are speculative variances among Class members and imaginary scenarios that do not reflect the undisputed facts of the common scheme implemented by Cephalon to market Actiq for non-cancer pain despite the safety risks and to flout the requirements of the RMP. Accordingly, the Motion to Exclude the Declaration and Testimony of Meredith Rosenthal should be denied.

II. FACTS

A. Summary of Cephalon's Undisputed Scheme to Reap the Benefits of Its Off-Label Marketing Campaign for Actiq

As reflected in Plaintiffs' Proffer of Facts In Support of Class Certification ("Proffer"),[1] Cephalon implemented an off-label marketing scheme to push physicians to prescribe Actiq for non-cancer pain, despite the fact that Actiq's risk and safety profile mandated that it "**ONLY** [be prescribed] for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying cancer pain."[2] Cephalon knew if it told the truth, *i.e.*, that Actiq was contraindicated for acute or post-operative pain and should never be used outside its approved indication, its sales would max out at the $15 million cancer pain market share achieved in 2000. So Cephalon purposefully devised a marketing plan to stay of Plaintiffs and the managed care class so that they would pay for Actiq for non-cancer pain.

[1] Plaintiffs incorporate the facts set forth in the Proffer and the Rebuttal Proffer of Facts in Support of Plaintiffs' Motion for Class Certification ("Rebuttal Proffer") as if fully set forth herein.

[2] Proffer, ¶ 19 (emphasis in original document published by the United States Food and Drug Administration ("FDA")).

Yet, as a condition of selling Actiq, Cephalon agreed with the FDA that it would monitor off-label prescribing and, if the off-label prescriptions exceeded 15%,[3] implement a proactive education campaign to stop physicians from prescribing Actiq for anything other than breakthrough cancer pain in cancer patients. Cephalon admits that it did not implement any education campaign – but nonetheless willingly accepted the benefits of the payments made by Plaintiffs and the Class for those off-label prescriptions. Plaintiffs seek a disgorgement of Cephalon's profits under a claim of unjust enrichment.

B. Dr. Rosenthal Calculated Damages for the Class Using the Data and Direction Produced by Cephalon

1. Dr. Rosenthal's qualifications to calculate damages in the form of Actiq-specific profits.

An economist at the Harvard School of Public Health, Dr. Rosenthal's principal research interests concern the economics of the healthcare industry including pharmaceuticals. Since 1996, she has worked on a number of consulting matters, most of which relate to litigation in healthcare markets generally and the pharmaceutical industry in particular. As a consultant, she has extensive experience analyzing both internal documents and transactional data maintained by pharmaceutical companies, including with respect to at least 23 prescription drugs, industry-wide prescription drug pricing, and prescriber identifiable data.[4]

Moreover, Dr. Rosenthal worked for several years as a Consultant for Price Waterhouse in the Tax Economics Department.[5] Both here and in her current work in the pharmaceutical

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[3] *See* Proffer §§ II.B.3, II.D for a discussion of the circumstances that should have triggered Cephalon's obligation to educate physicians to stop prescribing Actiq for non-cancer pain. These triggering circumstances were common to all Class members, do not implicate any individual Class member, focus solely on Cephalon's actions, and should be submitted to the trier of fact.

[4] Declaration of Meredith Rosenthal in Support of the Certification of the Class of End Payors of Actiq ("Rosenthal I").

[5] *See* Curriculum Vitae, Attachment A to Rosenthal I.

industry, she frequently uses profit and loss statements and balance sheets.[6] Based on her extensive experience with profit and loss statements generally, as well as her pharmaceutical industry work specifically, Dr. Rosenthal is qualified to calculate damages here.

2. Dr. Rosenthal calculated damages in the form of net profits for off-label sales of Actiq in excess of 15 percent of total prescriptions.

Plaintiffs retained Dr. Rosenthal for the following purpose:[7]

> For the purposes of recovery, I have been asked to calculate the amount of net profit earned by Cephalon from sales of Actiq resulting from the alleged off-label marketing practices and paid for by third-party payor Class members.

To calculate damages, Dr. Rosenthal relied on accounting data and information produced by the Defendant. To restrict profits to sales associated with allegedly illegal off-label marketing and to exclude non-Class sales, she also used publicly available data.[8]

Thus, for nearly one year, at Dr. Rosenthal's direction, Plaintiffs exhaustively sought all transactional data in Cephalon's possession, custody or control related to the revenues, costs and profits for Actiq for the purpose of calculating damages. The parties engaged in more than 40 oral and written meet and confers to identify the data possessed by Cephalon, the form in which it existed, the scope of the multiple datasets to be produced, and Cephalon's explanation of each dataset.[9]

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[6] *See* Ex. 25 (Transcript of Deposition of Meredith Rosenthal ("Rosenthal Tr."), at 12:23-13:2) to Declaration of Elizabeth A. Fegan In Support of Plaintiff's Reply in Support Of Motion for Class Certification and Response in Opposition To Motion to Exclude The Declaration and Testimony of Meredith Rosenthal ("Fegan Decl."). *See also* Rosenthal Tr. at 14:22-15:5, 15:13-16.

[7] Rosenthal I, ¶ 8.

[8] *Id.*, ¶ 10.

[9] *See* Fegan Decl.

During that process, Cephalon admitted

At the end of May 2012, Defendant's counsel advised that Plaintiffs had exhausted Cephalon's knowledge regarding the transactional data as it related to Actiq.[16]

Based on these answers, the raw transactional data, and her own observations regarding the data, Dr. Rosenthal calculated net profits for Actiq for the Class Period for the entire United States.[17]

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[10] Fegan Decl., ¶ 4.
[11] *See* generally *id.*
[12] *Id.*, ¶ 18.
[13] *Id.*, ¶ 18.
[14] *Id.*, ¶ 18.
[15] *Id.*, ¶ 21.
[16] *Id.*, ¶ 22.
[17] *See generally*, Rosenthal I. *See also* Rebuttal Declaration of Meredith Rosenthal ("Rosenthal II") filed contemporaneously herewith.

23

[18] Rosenthal II, ¶ 14.
[19] Rosenthal I, Attachment C.2.
[20]

The codes listed in the International Classification of Diseases (Ninth Revision) are referred to as ICD-9 codes.
[22] Rosenthal I, ¶ 15.
[23] Rosenthal I, ¶¶ 14-15.

After submitting her original report, and in response to Cephalon's Motion to Exclude, Dr. Rosenthal also reviewed and responded to the criticisms of her report set forth by Defendant's experts Christine Hammer, David Bradford and Michael Ashburn.[25]

III. ARGUMENT

Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The trial court is tasked with acting as a gatekeeper "to ensure that any and all expert testimony or evidence is not only relevant, but also reliable." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal quotation marks omitted); *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 (1993). To be admissible, such evidence must satisfy the three requirements set forth in Rule 702: (1) the proffered expert must be qualified; (2) the expert must give an opinion "about matters requiring scientific, technical, or specialized knowledge" which is derived from a reliable process or technique; and (3) the expert's testimony must "assist the trier

[24] Rosenthal I, ¶ 15.
[25] *See generally* Rosenthal II.

of fact," that is, it must "fit" the facts of the case. *Pineda*, 520 F.3d at 244; *In re Paoli R.R. Yard PCB Litig.* 35 F.3d 717, 741-43 (3d Cir. 1994).

A. Dr. Rosenthal is Qualified to Serve as an Expert for the Purpose of Calculating Damages

Under Rule 702, an expert witness is qualified by virtue of "specialized expertise." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). "The basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.'" *Id.* (citing *Waldorf v. Shuta*, 142 F.3d 601 (3d Cir. 1998)). Due to the liberal policy of admissibility under Rule 702, "a broad range of knowledge, skills, and training qualify an expert." *Paoli*, 35 F.3d at 741. The court need not find that the expert is "the best qualified" or his or her "specialization [to be the] most appropriate" to admit their testimony. *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996).

The Third Circuit has made clear:

> Because of our liberal approach to admitting expert testimony, most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony, than to its admissibility. Thus, witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified. Who is 'best' qualified is a matter of weight upon which reasonable jurors may disagree.

Holbrook, 80 F.3d at 782. Consistent with the Third Circuit's approach, Cephalon's contention that only a certified public accountant with specific expertise in cost accounting should be able to testify as to the Class's damages has been rejected. *Raytheon Co. v. United States*, 2009 U.S. Claims LEXIS 264, at *2 (Fed. Cl. May 13, 2009) (rejecting plaintiffs' request to disqualify the Government's actuarial expert on the grounds that he admittedly was not an expert in cost accounting standards and "had no hands-on experience in applying" that technique). "[T]he fact that [Dr. Rosenthal] has not specialized in cost accounting … goes to the weight, rather than the

admissibility, of [her] testimony." *Loussier v. Universal Music Grp., Inc.*, 2005 U.S. Dist. LEXIS 45430, at *15 (S.D.N.Y. June 28, 2005). "No case of which we are aware remotely suggests, let alone holds, that only a certified public accountant has the necessary expertise to testify about economic loss." *Loeffel Steel Prods. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 801-02 (N.D. Ill. 2005) (finding that an appraiser was qualified to calculate lost profits, stating: "The argument that only a CPA with expertise in the steel industry – preferably, with regard to multi-blanking machines and a prior history of expert testimony in a case involving lost profits due to a poorly performing piece of machinery – is inconsistent with the liberal approach to expert witness qualification taken by Rule 702.").

The fact that Dr. Rosenthal is an economist well-versed in pharmaceutical manufacturer data and not a certified public accountant with cost accounting experience does not disqualify her from calculating damages. Dr. Rosenthal's educational background and experience qualify her to testify about the profits made by a pharmaceutical manufacturer with respect to a particular drug. She has professional work experience working with profit and loss statements generally, and pharmaceutical manufacturer data specifically. Second, she has both educational and extensive work experience specifically in the pharmaceutical industry.[26] Accordingly, Dr. Rosenthal is qualified under Rule 702 to opine regarding damages.

B. Dr. Rosenthal's Calculation of Damages is Reliable Because It is Based on "Good Grounds"

Under the second prong of Rule 702, the court must determine whether "the process or technique the expert used in formulating the opinion is reliable." *Paoli*, 35 F.3d at 742. The standard for admissibility is a liberal one. The Federal Rules of Evidence "embody a strong preference for admitting any evidence that may assist the trier of fact." *Pineda*, 520 F.3d at 243.

[26] *See generally* Rosenthal I. *See also* Rosenthal II, ¶ 14.

Therefore, Plaintiffs "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." *Paoli*, 35 F.3d at 744. Pursuant to this liberal standard, an expert opinion will be admissible so long as it is based on "good grounds." *Id.* Where such good grounds exist, a trial judge "should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect." *Id.* at 746.

1. Dr. Rosenthal's analysis of the Actiq raw data informed by Cephalon's discovery responses and the Product Contribution Reports constitutes "good grounds" for her calculations.

Dr. Rosenthal was retained to calculate damages under an unjust enrichment theory. She explained the process she undertook to determine the method for calculating damages as follows:[27]

[27] Attachment C.2 to Rosenthal I.

29

Second, Cephalon ignores that Dr. Rosenthal expressly recognized that: [30]

For this very reason, in order to ensure that she did not blindly follow the Product Contribution Reports, Dr. Rosenthal explained she then:[31]

Even if this Court were concerned about Dr. Rosenthal's initial review of Cephalon's Product Contribution Reports, the Third Circuit has instructed that:

> the primary limitation on the judge's admissibility determinations is that the judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks "good grounds" for his or her conclusions.

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[28] Rosenthal II, ¶ 14.
[29] Rosenthal II, ¶¶ 13-14.

Attachment C.2 to Rosenthal I.

Rosenthal II, ¶¶ 13-14.
[31] Attachment C.2 to Rosenthal I (emphasis added).

Paoli, 35 F.3d at 746. Accordingly, Cephalon's contention that Dr. Rosenthal's entire opinion is flawed merely because she started with documents produced by Cephalon should be rejected. Dr. Rosenthal used all of the raw data produced by Cephalon, as well as Cephalon's discovery responses, to calculate damages.

2. Dr. Rosenthal's allocation of costs is reasonable under the circumstances.

Cephalon nonetheless contends that Dr. Rosenthal should have created a profit and loss statement under cost accounting principles in the same way Cephalon would have for internal business purposes. However, Cephalon ignores that Dr. Rosenthal's task was to calculate damages for the Class under a theory of disgorgement – for this purpose, the calculation of incremental profits (a/k/a product contribution margin or product-specific profits) is appropriate.

As Dr. Rosenthal explained:[32]

* * *

[32] Rosenthal II, ¶¶ 8, 10-12.

The RESTATEMENT 3D OF RESTITUTION AND UNJUST ENRICHMENT § 51 ("Enrichment by Misconduct; Disgorgement; Accounting") ("RESTATEMENT"), is on point. Section 51 of the RESTATEMENT provides in pertinent part:

> (4) … the unjust enrichment of a conscious wrongdoer … is the net profit attributable to the underlying wrong. The object of restitution in such cases is to eliminate profit from wrongdoing while avoiding, so far as possible, the imposition of a penalty. Restitution remedies that pursue this object are often called "disgorgement" or "accounting."
>
> (5) **In determining net profit the court may apply such tests of causation and remoteness, may make such apportionments, may recognize such credits or deductions, and may assign such evidentiary burdens, as reason and fairness dictate, consistent with the object of restitution as specified in subsection (4).**
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> * * *

> (d) A claimant who seeks disgorgement of profit has the burden of producing evidence permitting at least a reasonable approximation of the amount of the wrongful gain. Residual risk of uncertainty in calculating net profit is assigned to the defendant.

RESTATEMENT § 51. Consistent with the RESTATEMENT, Dr. Rosenthal has calculated a "reasonable approximation of the amount of the wrongful gain." *Id.*

Dr. Rosenthal conducted an extensive investigation into the data maintained by Cephalon and conducted a categorical review to determine the proper allocation of costs to Actiq for purposes of calculating damages. The question of whether Dr. Rosenthal should have allocated additional costs to Actiq is a question for the jury, and not a basis on which to disqualify her opinion as unreliable.

Cephalon's contention that Dr. Rosenthal failed to consider certain categories of cost is an issue that goes to the weight of her opinion, not to the admissibility. The court's analysis in *City of St. Petersburg v. Total Containment, Inc.*, 2009 U.S. Dist. LEXIS 101367 (S.D. Fla. Mar. 19, 2009), is instructive. There, the plaintiff proffered an expert witness on plaintiffs' lost profits. In his calculation, plaintiffs' expert "included the cost of goods and costs directly associated with the sale of products, consistent with accepted methodology" and excluded "home office or fixed costs." *Id.* at *38-39. Defendants sought to exclude the expert's testimony because he failed to take into account these fixed – or overhead – costs. *Id.*

Rejecting the Defendant's motion, the court explained:

> We deny Defendants' motion to exclude Dr. McClave as an expert witness on Plaintiffs' lost profits. He is qualified to so testify, based on his education, training, and experience, and his methodology is reliable. While Defendants may believe there are other expenses that Dr. McClave should have considered in his analysis, this is more of a challenge to the accuracy of the resulting calculation, not necessarily to the methodology he employed to arrive at the calculation. This is what cross-examination at trial

> will highlight, but it is not enough to exclude the expert's analysis altogether.

City of St. Petersburg, 2009 U.S. Dist. LEXIS 101367, at *14.[33] *See also* George P. Roach, "Counting the Beans: Unjust Enrichment and the Defendant's Overhead," 16 TEX. INTELL. PROP. L.J. 483, 498 (Spring 2008) (the allocation of costs "is a question of fact in all cases"). This case is directly analogous here.

While Cephalon may believe Dr. Rosenthal should have considered or deducted additional costs in the data, Cephalon will have the opportunity to present those costs to the jury for consideration in the damages phase. Given that Dr. Rosenthal conducted a thoughtful analysis based on her own experience and Cephalon's discovery responses, Cephalon's challenge is more to the weight of her testimony than to the actual methodology.

Moreover, as one commentator noted, the deduction of the fixed costs espoused by Cephalon would improperly inure to Cephalon's benefit:

> the American history of the development of measuring unjust enrichment shows that all advantages to the defendant should be disgorged, whether or not the advantages would normally be included in any accounting definition of "profit." Accordingly, deducting allocations of the defendant's fixed costs in the measure of her benefit or advantage will allow her to retain a significant advantage or the possibility of advantage.

Roach, *Counting the Beans*, 16 TEX. INTELL. PROP. L.J. 483 at 488. Thus, courts do not exclude an expert's calculation of damages based on whether the expert followed cost accounting principles. *See, e.g.,In r e Matteson Marine Serv.*, 2011 U.S. Dist. LEXIS 75168, at *66-67 (C.D. Ill. July 13, 2011) ("'One of the great dangers in allocating common fixed costs is that such allocations can make a product line (or other segment of a business) look less profitable than it really is.' *See also, Kansas Gas & Elec. Co. v. U.S.*, 95 Fed. Cl. 257, 308 (2010) ('The

[33] In fact, Cephalon did not cite to a single case for its contention that Dr. Rosenthal's report should be stricken because of costs she purportedly did not consider.

court has no quarrel with [the expert witnesses'] characterization of [the claimant's] use of … cost accounting for business purposes [as reasonable] …. However, what makes for good business accounting does not translate automatically into a fair and reasonable apportionment of damages.')").

In the Third Circuit, "[t]he grounds for the expert's opinion merely have to be good, they do not have to be perfect." *Paoli*, 35 F.3d at 744. This simply is not a case where an expert offers an opinion completely devoid of any factual basis. *See Elcock v. Kmart Corp.*, 233 F.3d at 754-56. *See also University of Colo. Found., Inc. v. American Cyanamid Co.*, 342 F.3d 1298, 1312 (Fed. Cir. 2003) (holding that district court did not err in its finding that "Professor Rubinfeld, an expert economist, ably addressed the amount of profits to be returned, performing an analysis that calculated the incremental profits, i.e., sales less production and marketing/distribution costs, of [the drug] Cyanamid that were attributable to the right to exclude generic competition," for purposes of damages under a theory of unjust enrichment.). Rather, Dr. Rosenthal "applied [her] economic expertise to calculate [] profits based on information that [s]he collected from a variety of sources and on which [s]he reasonably relied." *Bennington Foods, LLC v. St. Croix Renaissance Grp., LLLP*, 2009 U.S. Dist. LEXIS 115414, at *13-14 (D.V.I. Dec. 9, 2009) (citations omitted). Accordingly, Cephalon's motion should be denied.

3. Dr. Rosenthal did not opine on causation.

Cephalon wastes three pages contending Dr. Rosenthal's causation opinion is unreliable. Def. Br. at 11-14. Dr. Rosenthal was not retained to and did not opine on causation. Rather, Dr. Rosenthal was asked to calculate damages for Actiq. Courts are clear that *Daubert* permits a

damages expert to assume causation. *Rmd v. NiHo Ams., Inc.*, 2012 U.S. Dist. LEXIS 158107, at *29-30 (D. Kan. Nov. 5. 2012).[34]

In *Rmd*, the defendants filed a motion to strike the plaintiff's damages expert, contending "his methodology is flawed because he assumes causation." *Id.* at *9. Denying defendant's motion, the court explained:

> Vianello is not a causation expert. His expert testimony relates only to damage calculation, not to causation. … Vianello assumed causation based on the evidence that was presented to him by Plaintiff. ***For purposes of presenting his damage calculation methods, however, Vianello is permitted to presume causation***, which is a prerequisite to recovery that will have to be established at trial by evidence other than Vianello's testimony. The issue of whether a breach occurred is clearly an element of Plaintiff's case, which Plaintiff readily accepts the burden of proof at trial. ***Vianello may show that his calculations are consistent with Plaintiff's theory of causation, and thus Defendants' objection is overruled.***

Id. at *29-30 (emphasis added). None of the cases cited by Cephalon contradict the established notion that damages experts are permitted to assume causation.[35] Just as in *Rmd*, Dr. Rosenthal is permitted to presume causation.

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[34] *See also U.S. ACCU-Measurements, LLC v. Ruby Tuesday. Inc.*, 2013 U.S. Dist. LEXIS 59888, at *12-13 (D.N.J. Apr. 26, 2013) (denying motion to exclude damages expert who assumed plaintiffs' version of the facts was true, explaining: "What [defendant] calls "legal conclusions" are really this damages expert's assumptions as to the substance of a breach of contract claim that may (or may not) be established at trial."); *CDW LLC v. NETech Corp.*, 2012 U.S. Dist. LEXIS 140340 (S.D. Ind. Sept. 28, 2012) (noting that proximate cause must be established through evidence independent of the damages expert and denying motion to exclude the damages expert based on the fact he assumed causation); *Sleepy's, LLC v. Select Comfort Wholesale Corp.*, 2012 U.S. Dist. LEXIS 17079, at *6 (E.D.N.Y. Feb. 10, 2012) (denying motion to strike damages expert for assuming causation, and stating: "Causation in this case presents a question of fact."); *Univac Dental Co. v. Dentsply Int'l, Inc.*, 2010 U.S. Dist. LEXIS 26852 (M.D. Pa. Jan. 20, 2010) (denying motion to strike damages expert who assumed causation); *Talmage v. Harris*, 354 F. Supp. 2d 860, 868 (W.D. Wis. 2005) (denying motion to strike damages expert who assumed causation and stating: "The [causation] issues raised by defendants' motion are for the jury to resolve.").

[35] *See* Def. Br. at 11-14 (citing *In re TMI Litig.*, 193 F.3d 613, 677 (3d Cir. 1999) (affirming the trial court's decision to exclude a causation expert); *Legendary Art, LLC v. Godard*, 2012

Cephalon's arguments regarding causation focus, in part, on Dr. Rosenthal's exclusion of profits attributable to 15% of off-label sales at the direction of counsel (based on the RMP). In calculating damages, Dr. Rosenthal could have merely ended her calculations at "Net Profits Attributable to Third Party Payors" (excluding governmental payors) which exceeded

However, Plaintiffs have always been very clear in their theory of liability: unlike in other off-label marketing cases, Cephalon had a back-end obligation to take mandated steps to halt off-label sales once they exceeded 15%. Thus, to be conservative, Plaintiffs instructed Dr. Rosenthal as follows:[37]

Ultimately, the correct interpretation of the Risk Management Program – and the 15% – is a class-wide issue for the jury. The use of the 15% merely reflects that the damage calculations are consistent with Plaintiffs' theory for trial. *Rmd*, 2012 U.S. Dist. LEXIS 158107, at *29-30.

U.S. Dist. LEXIS 116270 (E.D. Pa. Aug. 17, 2012) (in this case, the expert was not excluded because he assumed causation but because the limited data on which he relied was unreliable); *Chemipal Ltd. v. Slim-Fast Nutritional Foods Int'l*, 350 F. Supp. 2d 582 (D. Del. 2004) (in this case, the expert was not excluded because he assumed causation but because of the lack of relevant data on which he calculated damages); *Apple, Inc. v. Motorola, Inc.*, 2012 U.S. Dist. LEXIS 105387 (N.D. Ill. May 22, 2012) (in this case, the expert was not excluded because he assumed causation but because of the lack of relevant data on which he calculated damages)).

[36] Rosenthal I, Attachment C.1.

[37] Rosenthal I, Attachment C.2.

4. Dr. Rosenthal's use of the IMS NDTI data is reliable and fits the specific facts of this case.

Cephalon attacks Dr. Rosenthal's reliance on NDTI data for calculating the percentage of off-label sales of Actiq. However, NDTI data is the gold standard for analyzing prescription levels in the United States.

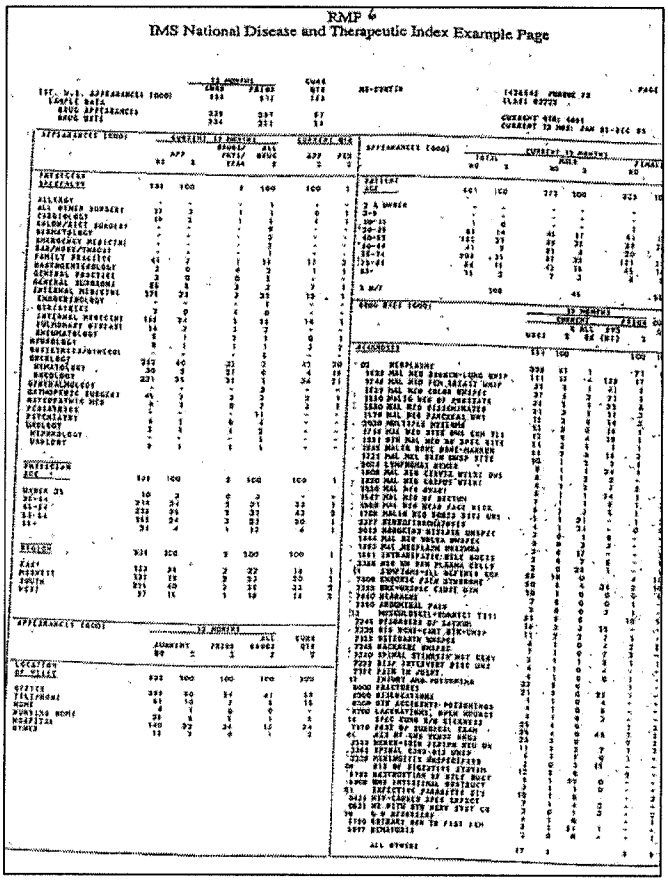
a. The FDA mandated that Cephalon monitor and analyze the NDTI prescription data for Actiq.

The Actiq Risk Management Program (November 4, 1998) was very specific about the prescription data to be monitored by the manufacturer (ultimately Cephalon). Section 8.2.2 of the RMP provided:[38]

> National prescription data segmented by physician specialty and by indication from IMS National Disease and Therapeutic Index (NDTI) will be analyzed.

To ensure there was no confusion, the RMP further provided: "An example of an NDTI data sheet is attached as RMP Attachment 6."[39] Attachment 6 to the RMP follows:

[38] Proffer of Facts in Support of Class Certification, Ex. 4, § 8.2.2, at 23.
[39] *Id.*


RMP 6
IMS National Disease and Therapeutic Index Example Page

Thus, the FDA was clear that the monitoring of prescriptions of Actiq should occur through the NDTI data.

Moreover, in order to obtain the FDA's approval of Actiq, the original manufacturer of Actiq provided assurances to the FDA's Center For Drug Evaluation And Research Anesthetic And Life Support Drugs Advisory Committee regarding how the NDTI data would be used: [40]

[40] Rebuttal Proffer of Facts, Ex. ¶¶ 15-16 (Transcript of Meeting before the Food and Drug Administration's Center For Drug Evaluation And Research Anesthetic And Life Support Drugs Advisory Committee (September 17, 1997), at 100). *See also id.* at 196 (The original manufacturer of Actiq testified: "I mentioned this morning that we were going to be doing an ongoing monitoring of different surveillance programs that are out there, and … NDTI … will give us information, as I said, on a quarterly basis as to who's prescribing the drug for what indication. And you can check very easily there and see whether the oncologists are prescribing Actiq™ or whether dermatologists – terrible thought – would be prescribing Actiq™. So that will give us an indication of whether or not it's being used appropriately.).

> We have what we call a quality assurance program which is really our vigilance program, and how we're going to monitor how this drug is used. There are a variety of surveillance programs that we will be using, including national databases such as the NDTI and the NPA which are programs that routinely track how drugs are being prescribed, who's prescribing them, what the diagnosis is.
>
> And through looking at this in a quarterly basis and an annual basis, we can determine whether inappropriate clinicians are prescribing *Actiq*™.

Thus, the FDA and the manufacturer agreed that the NDTI data would be monitored and used for assessing compliance with the RMP. For that reason alone, it was reasonable for Dr. Rosenthal to use the same NDTI data to calculate the percentage of off-label use for purposes of damages.

b. IMS data, including NDTI data, is generally accepted in the industry and considered the "Gold Standard."

Cephalon admits that NDTI data published by IMS Health is reliable, Def. Br. at 15, but wishes to parse generally-accepted reliability from the facts of this case. However, IMS's NDTI data is generally accepted in the industry as reliable for evaluating prescribing habits.[41]

Dr. Rosenthal explains that:[42]

> NDTI data are the gold standard for the estimation of national prescription medication use linked to specific diagnoses and related to promotional activities in academic, government and industry research and forecasting. The methods employed to present this information in my Declaration are standard practice in the relevant peer reviewed literature.

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[41] Rosenthal II, ¶¶ 18-20. *See also* David, "The Effects of Pharmaceutical Marketing and Promotion on Adverse Drug Events and Regulation," *American Economic Journal: Economic Policy 2* (Nov. 2010): 1-25, *available at* http://www.aeaweb.org/articles.php?doi=10.1257/pol.2.4.1 ("The NDTI is a nationally representative sample of office-based physicians in private practice in the United States.").

[42] Rosenthal II, ¶ 18.

Dr. Rosenthal explains that NDTI data have been the:[43]

> the foundation of prescription use estimates by many peer reviewed publications to provide national estimates of the uses of prescription medications overall and by specific classes and compounds linked to diagnoses, in esteemed journals such as the Journal of the American Medical Association (JAMA) and the Archives of Internal Medicine for decades. NDTI data have been commonly used to estimate national prescription use related to off-label indications found in peer reviewed publications.

Cephalon's own expert, David Bradford, has also published studies based on IMS data.[44]

IMS NDTI data are used by the Food and Drug Administration (FDA) to assess drug use in the U.S.[45] IMS products, including NDTI, are also widely used by the pharmaceutical industry to estimate national prescription drug utilization and national trends over time.[46] And courts have recognized that IMS data is the "gold standard" for purposes of calculating damages on

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[43] Rosenthal II, ¶ 19. Dr. Rosenthal also explains in her Rebuttal Report that Defendant's attacks on the reliability of the NDTI data are misplaced. Rosenthal II, ¶¶ 21-24.

[44] *See, e.g., Bradford, et al.*, How Direct-To-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior, 25 HEALTH AFFAIRS 1371-77, at 1376 (Sept./Oct. 2006) ("There are a number of possible explanations for the lack of an own-effect from Celebrex DTC advertising. For example, data from IMS Health indicate that Pfizer devoted relatively more effort in 2000 to direct-to-physician marketing for Celebrex in the form of visits by pharmaceutical representatives, who provided samples (known in the industry as detailing) than Merck did on behalf of Vioxx.").

[45] Rosenthal II, ¶ 19. *See also* Press Release, "IMS Government Solutions Signs $3.8 million, 5-year contact with the U.S. Food and Drug Administration," (December 7, 2012), available at http://www.imsgovt.com/ResourceLibrary/IMSNews.aspx ("Under the terms of the contract, IMS Health will provide the FDA with access to data on pharmaceutical sales that will allow the FDA to respond expeditiously to questions relating to drug safety, the impact of regulatory policies and to potential drug shortage situations) (last accessed May 15, 2013); Press Release, "IMS HEALTH Awarded Five-Year Services Contract By U.S. Food And Drug Administration," (March 14, 2001), available at http://www.ims-health.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c033208c22a/?vgnextoid=9a181d3be7a29110VgnVCM10000071812ca2RCRD&vgnextchannel=4eb65890d33ee210VgnVCM10000071812ca2RCRD&vgnextfmt=default (last accessed May 15, 2013) (stating "Under a new five-year contract, the FDA will use an array of IMS HEALTH market research services to improve its knowledge of drug use and the impact of pharmaceutical products on patient outcomes," and noting the data to be used by the FDA includes NDTI data).

[46] Rosenthal II, ¶ 19.

behalf of third-party payors. *New Eng. Carpenters Health Benefits Fund v. First Databank, Inc.*, 248 F.R.D. 363, 370 (D. Mass. 2008).

For example, in *New Eng. Carpenters Health Benefits Fund*, the court considered and rejected defendant's objections to plaintiffs' use of IMS data, stating:

> [A]ccording to Dr. Hartman, IMS data "is one of the most, if not the most, frequently used sources of data summarizing a variety of business transactions, strategic behavior and corporate activity of pharmaceutical manufacturers." Peer-reviewed journals have relied on IMS NPA data. Many courts have relied on IMS data in litigation involving the pharmaceutical markets. *See, e.g.,In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 526 (E.D. Mich. 2003) (holding, for settlement purposes, the Plaintiffs used IMS data to "make an informed judgment of … the potential damages arising" from the alleged antitrust violation); *see also Neurontin*, 244 F.R.D. at 110-11. In Hartman's words, IMS data have been considered the "gold standard for reasonable measurement of reimbursement by end payors, including TPPs."

Id. at 370 (citations omitted). Accordingly, this Court should deny Defendant's motion.

C. Dr. Rosenthal's Opinion Will Assist the Trier of Fact in Measuring the Class's Damages

For the third prong, the expert's testimony must "assist the trier of fact," that is, it must "fit" the facts of the case. *Pineda*, 520 F.3d at 244; *Paoli*, 35 F.3d at 741-43. Here, Dr. Rosenthal calculated the incremental profits attributable to Actiq for the purposes of disgorgement, which will assist the trier of fact in considering the Class's damages. *Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs.*, 546 F. Supp. 2d 155, 174 (D.N.J. 2008). In *Floorgraphics, Inc.*, the court rejected defendant's motion to exclude plaintiffs' expert report calculating damages and explained:

> In order to "be fit", expert testimony "must have a traceable and analytical basis in objective fact." *Bragdon v. Abbott*, 524 U.S. 624, 653, 118 S. Ct. 2196, 141 L. Ed. 2d 540 (1998). Mr. Wills' testimony is based upon the actual sales of Plaintiff. Without his testimony, the jury will have a difficult time in measuring Plaintiff's damages. Since this is a complex matter that requires a

> detailed economic analysis, Mr. Wills' testimony will be helpful. Under Rule 702, it is not the Court's province to determine who is the best expert or the most qualified. Defendants will have the opportunity to vigorously cross-exam Mr. Wills in addition to presenting their own expert witness at trial. Therefore, Defendants' motion to preclude Mr. Wills' testimony is denied.

546 F. Supp. 2d at 174. Like in *Floorgraphics,* Dr. Rosenthal's testimony has a traceable and analytical basis in objective fact. It is based on Cephalon's own data, Cephalon's instructions regarding the data, and her own experience in working with pharmaceutical manufacturer's data.

Cephalon contends that Dr. Rosenthal's opinion does not fit because she does not consider what it calls the "equities." First, Cephalon has not cited a single case for the proposition that an expert calculating damages for an unjust enrichment claim must consider alleged equities. Second, the equities espoused by Cephalon have no basis in fact. Trying to fit a round peg into a square hole, Cephalon contends the equities include speculative variances among Class members or TPP decisions, and individual circumstances of prescribing decisions. As reflected in Plaintiffs' Reply In Support of Class Certification and the accompanying expert declaration from Thomas McGuire, those issues are irrelevant under the law.[47] Moreover, those purported variances have no basis in fact.[48]

Finally, Cephalon contends that Dr. Rosenthal has not attempted to calculate damages for Plaintiffs' alternative classes. In fact, the methodology for calculating the net profits attributable to Actiq would not differ by state. The only additional step to be taken would be apportionment based on the percentage of sales of Actiq per state through publicly-maintained data.[49]

Cephalon's reliance on cases where the experts had not yet even formulated a model for calculating damages are thus inapplicable. Rather, courts in this District have found plaintiffs'

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[47] Reply in Support of Class Certification; Declaration of Thomas McGuire ("McGuire Decl.").

[48] *See* McGuire Decl.

[49] Rosenthal II, ¶ 25.

methodologies to be sufficient where plaintiffs have calculated nationwide damages based on the defendant's data, and state-specific damages can be calculated using publicly-available data reflecting the number of prescriptions per state. *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 233 (E.D. Pa. 2012). As Judge Brody recognized:

> This methodology would rely on common evidence in the form of profit and loss statements for Flonase possessed by GSK. [Plaintiff's expert] further explained that this data could be adjusted to calculate state-specific damages by relying on available state-specific data on FP prescriptions and their penetration in the class state markets.
>
> Neither of GSK's experts challenged the reliability of Rausser's proposed methodology to calculate unjust enrichment damages in Arizona, Massachusetts, and Wisconsin. GSK asserts that because Rausser has failed to show an actual calculation of unjust enrichment damages, based on his proposed methodology, his methodology is unreliable and incapable of measuring class-wide damages. However, at this stage of the litigation, this bare contention is simply insufficient.

Flonase, 284 F.R.D. at 233. Like in *Flonase*, Cephalon's bare contention is insufficient. In fact, Dr. Rosenthal has calculated damages for the Class. Apportionment of the damages by state is merely a mathematical calculation based on publicly-available date.[50] Accordingly, this Court should deny Cephalon's motion.

IV. CONCLUSION

Plaintiffs respectfully request that the Court deny Defendant's Motion to Exclude the Declaration and Testimony of Meredith Rosenthal, and grant such other and further relief as this Court deems appropriate.

[50] Rosenthal II, ¶ 25.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that on May 24, 2013, a true and correct redacted copy of the foregoing PLAINTIFFS' RESPONSE IN OPPOSITION TO MOTION TO EXCLUDE THE DECLARATION AND TESTIMONY OF MEREDITH ROSENTHAL, was filed via CM/ECF, which caused notice to be delivered to all counsel of record. Additionally, Plaintiffs have filed an unredacted version under seal, with copies to counsel of record.

/s/ Elizabeth A. Fegan